

PATENT APPLICATION

STENT FOR PLACEMENT AT LUMINAL OS

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STENT FOR PLACEMENT AT LUMINAL OS

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/463,075 (Attorney Docket No. 015471-000900US), filed on April 13, 2003, the full disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention. The present invention relates generally to medical devices and methods. More particularly, the present invention relates to the structure and deployment of a segmented stent at a luminal os at a branching point in the vasculature or elsewhere.

[0003] Maintaining the patency of body lumens is of interest in the treatment of a variety of diseases. Of particular interest in the to the present invention are the transluminal approaches to the treatment of body lumens. More particularly, the percutaneous treatment of atherosclerotic disease involving the coronary and peripheral arterial systems. Currently, percutaneous coronary interventions (PCI) involve a combination of balloon dilation along with the placement of an endovascular prosthesis commonly referred to as a stent. A major limitation of PCI/stent procedure is restenosis, i.e., the re-narrowing of a blockage after successful intervention typically occurring in the initial three to six months. The recent introduction of drug eluting stents (DES) has dramatically reduced the incidence of restenosis in coronary vascular applications and offers promise in peripheral stents, venous grafts, arterial and prosthetic grafts, as well as A-V fistulae. In addition to vascular applications, stents are being employed in treatment of other body lumens including the gastrointestinal systems (esophagus, large and small intestines, biliary system and pancreatic ducts) and the genital-urinary system (ureter, urethra, fallopian tubes, vas deferens).

[0004] While quite successful in treating arterial blockages and other conditions, most stent designs are challenged when used at a bifurcation in the blood vessel or other body lumen being treated. Presently, many different strategies are employed to treat bifurcation lesions with currently available stents all of which have major limitations.

[0005] One common approach is to place a conventional stent in the main or larger body lumen over the origin of the side branch. After removal of the stent delivery balloon, a

second wire is introduced through a cell in the wall of the deployed stent and into the side branch. A balloon is then introduced into the side branch and inflated to enlarge the side-cell of the main vessel stent. This approach appears to work well when the side branch is relatively free of disease, although it is associated with increased rates of abrupt closure due to plaque shift as well as increased rates of late re-restenosis.

[0006] Another commonly employed strategy is the ‘kissing balloon’ technique in which separate balloons are positioned in the main and side branch vessels and simultaneously inflated. This technique is thought to prevent plaque shift.

[0007] Various two stent approaches including Culotte, T-Stent and Crush Stent techniques have been employed as well. When employing a T-stent approach, the operator deploys a stent in the side branch followed by placement of a main vessel stent. This approach is limited by anatomic variation (angle between main and side branch) and inaccuracy in stent positioning, which together can cause inadequate stent coverage of the os. More recently, the Crush approach has been introduced in which the side-vessel stent is deployed across the os with portions in both the main and side branch vessels. The main vessel stent is then delivered across the origin of the side branch and deployed, which results in crushing a portion of the side branch stent against the wall of the main vessel. Following main-vessel stent deployment, it is difficult and frequently not possible to re-enter the side branch after crush stenting. Unproven long-term results coupled with concern regarding the inability to re-enter the side branch and the impact of three layers of stent (which may be drug eluting) opposed against the main vessel wall has limited the adoption of this approach.

[0008] These limitations have led others to develop stents specifically designed to treat bifurcation lesions. One approach employs a stent design with a side opening for the branch vessel which is mounted on a specialized delivery balloon. The specialized balloon delivery system accommodates wires for both the main and side branch vessels. The system is tracked over both wires which provides a mean to axially and radially align the stent/stent delivery system. The specialized main vessel stent is then deployed and the stent delivery system removed while maintaining wire position in both the main and side branch vessels. The side branch is then addressed using kissing balloon or by delivering and an additional stent to the side branch. Though this approach has many theoretic advantages, it is limited by difficulties in tracking the delivery system over two wires (Vardi et al, 6,325,826 and 6,210,429).

[0009] For these reasons, it would be desirable to provide improved prostheses and methods for their placement to treat body lumens at or near the location of an os between a main body lumen and a side branch lumen, typically in the vasculature, and more particularly in the arterial vasculature. It would be further desirable if such prostheses and methods could
5 treat the side branch vessels substantially completely in the region of the os and that the prostheses in the side branches be well-anchored at or near the os. At least some of these objectives will be met by the inventions described hereinbelow.

[0010] 2. Description of the Background Art. Stent structures intended for treating bifurcated lesions are described in U.S. Patent Nos. 6,599,316; 6,596,020; 6,325,826; and
10 6,210,429. Other stents and prostheses of interest are described in the following U.S. Patent Nos. 4,994,071; 5,102,417; 5,342,387; 5,507,769; 5,575,817; 5,607,444; 5,609,627; 5,613,980; 5,669,924; 5,669,932; 5,720,735; 5,741,325; 5,749,825; 5,755,734; 5,755,735; 5,824,052; 5,827,320; 5,855,598; 5,860,998; 5,868,777; 5,893,887; 5,897,588; 5,906,640; 5,906,641; 5,967,971; 6,017,363; 6,033,434; 6,033,435; 6,048,361; 6,051,020; 6,056,775;
15 6,090,133; 6,096,073; 6,099,497; 6,099,560; 6,129,738; 6,165,195; 6,221,080; 6,221,098; 6,254,593; 6,258,116; 6,264,682; 6,346,089; 6,361,544; 6,383,213; 6,387,120; 6,409,750; 6,428,567; 6,436,104; 6,436,134; 6,440,165; 6,482,211; 6,508,836; 6,579,312; and 6,582,394;

BRIEF SUMMARY OF THE INVENTION

[0011] The present invention provides improved prostheses and methods for their
20 placement at an os opening from a main body lumen to a branch body lumen. The prostheses and methods will be principally useful in the vasculature, most typically the arterial vasculature, including coronary, peripheral, venous grafts, arterial and prosthetic grafts, as well as A-V fistulae. In addition to these vascular applications the present invention will also
25 be useful in the treatment of other body lumens including the gastrointestinal systems (esophagus, large and small intestines, biliary system and pancreatic ducts) and the genital-urinary system (ureter, urethra, fallopian tubes, vas deferens), and the like.

[0012] The prostheses of the present invention are particularly advantageous since they permit substantially complete coverage of the wall of the branch body lumen up to the lumen
30 os. Additionally, the prostheses have integrated anchoring components which expandably conform to and at least partially circumscribe the wall of the main body vessel to selectively and stably position the prosthesis within the side branch lumen. The anchoring components

may be fully expanded to open the luminal passage through the main branch lumen. Such complete opening is an advantage since it provides patency through the main branch lumen. Moreover, the open main branch lumen permits optional placement of a second prosthesis within the main branch lumen using conventional techniques.

5 [0013] In a first aspect of the present invention, a prosthesis comprises a radially expansible scaffold and at least two "circumferential" anchors extending axially from an end of the scaffold. The anchors are adapted to "expandably circumscribe" a portion of, usually at least one-half of the circumference main vessel wall at or near the os when the scaffold is implanted in the main lumen with one end of the scaffold adjacent the os. By "expandably
10 circumscribe," it is meant that the anchors will extend into the main body lumen after initial placement of the scaffold within the branch body lumen. The circumferential anchors will be adapted to then be partially or fully radially expanded, typically by expansion of a balloon or other expandable element therein, so that the anchors deform outwardly and engage the interior of the main lumen wall.

15 [0014] The circumferential anchors will usually extend axially within the main vessel lumen for some distance after complete deployment. Thus, the contact between the anchors and the main vessel wall will usually extend both circumferentially (typically covering an arc equal to one-half or more of the circumference) and axially.

[0015] Expansion of the circumferential anchors at least partially within the main body
20 lumen provides a generally continuous coverage of the os from the side body lumen to the main body lumen. Further and/or complete expansion of the circumferential anchors within the main body lumen may press the anchors firmly against the main body lumen wall and open up the anchors so that they do not obstruct flow through the main body lumen.

[0016] Usually, the prosthesis will include at least three circumferential anchors extending
25 axially from the end of the scaffold. The prosthesis could include four, five, or even a greater number of circumferential anchors, but the use of three such anchors is presently preferred since a greater number could interfere with subsequent access by the second expansion balloon. The circumferential anchors will have an initial length (i.e., prior to radial expansion of the scaffold) which is at least 1.5 times the width of the scaffold prior to expansion,
30 typically being at least 2 times the width, more typically being at least 5 times the width, and often being 7 times the width or greater. The lengths will typically be at least 2 mm, preferably being at least 3 mm, and more preferably being at least 6 mm, depending on the

diameter of the scaffold and prosthesis. The circumferential anchors will usually have a width which is expandable to accommodate the expansion of the scaffold, and the anchors may be "hinged" at their point of connection to the scaffold to permit freedom to adapt to the geometry of the main vessel lumen as the prosthesis is expanded. It is also possible that the anchors could be attached to the single point to the scaffold, thus reducing the need for such expandability. The anchors may be congruent, i.e., have identical geometries and dimensions, or may have different geometries and/or dimensions. In particular, in some instances, it may be desirable to provide anchors having different lengths and/or different widths.

[0017] Often, radiopaque or other visible markers will be placed on the prostheses and/or delivery balloon at desired locations. In particular, it may be desirable to provide radiopaque markers at or near the location on the prosthesis where the scaffold is joined to the circumferential anchors. Such markers will allow a transition region of the prosthesis between the scaffold and the anchors to be properly located near the os prior to scaffold expansion. Note that it is also possible to provide the radiopaque or other markers on a balloon or other delivery catheter, where the markers would also be aligned with the transition region between the scaffold and the circumferential anchors.

[0018] In a second aspect of the present invention, a prosthesis is deployed across an os opening from the main body lumen to a branch body lumen. The prosthesis is positioned so that a scaffold of the prosthesis lies within the branch body lumen and at least two, typically at least three, circumferential anchors extend from the scaffold at the os into the main body lumen. The scaffold is radially expanded to implant the scaffold in the branch body lumen. While at least some of the anchors may initially obstruct the lumen, the anchors are subsequently circumferentially deformed (usually after expansion of the scaffold) to circumscribe at least a portion of the main vessel wall, with at least one anchor typically covering at least 50% of the circumferential length, preferably at least 60% of the circumferential length and often at least 75% or greater. In this way, the circumferential anchors will open a passage through the anchors and the main body lumen to permit generally unobstructed blood flow or flow of other body fluids. Positioning of the prosthesis will usually comprise aligning a visible marker on at least one of the prosthesis and delivery balloon with the os so that the prosthesis is properly positioned relative to both the side branch lumen and the main body lumen.

[0019] In an exemplary deployment protocol, the scaffold is first expanded with a balloon catheter positioned within the scaffold. The balloon catheter expands the scaffold within the branch body lumen and usually begins separating and deploying the circumferential anchors within the main body lumen. After the scaffold has been deployed, the anchors are deformed to circumscribe the wall of the main body lumen, typically using a balloon positioned transversely through the anchors. In some instances, the scaffold and the circumferential anchors may be expanded and deformed using the same balloon, e.g., the balloon is first used to expand the anchor, partially withdrawn, and advanced transversely through the circumferential anchors where it is expanded for a second time. Alternatively, separate balloon catheters may be employed for expanding scaffold within the side branch and deforming the circumferential anchors within the main body lumen.

[0020] Optionally, a second prosthesis may be deployed within the passage formed through the circumferential anchors. For example, the second prosthesis may be deployed by a balloon catheter exchanged over a guidewire pre-positioned for deformation of the anchors. Alternatively, although less preferable, the anchors may be deformed by deployment of the second prosthesis in order to reduce the procedure by one step.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] Fig. 1 is a schematic illustration of a prosthesis constructed in accordance with the principles of the present invention.

[0022] Fig. 1A is a detailed view of an anchor of the prosthesis of Fig. 1, shown with the anchor deployed in broken line.

[0023] Fig. 2 is a cross-sectional view taken along line 2-2 of Fig. 1.

[0024] Fig. 3 is a "rolled-out" illustration of an exemplary prosthesis constructed in accordance with the principles of the present invention.

[0025] Figs. 4A-9B illustrate deployment of a stent at an os between a main blood vessel and a side branch blood vessel in accordance with the principles of the methods of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0026] Referring to Figs. 1 and 2, a stent 10 constructed in accordance with the principles of the present invention includes at least a radially expansible scaffold section 12 and an anchor section 14. The anchor section 14 includes at least two axially aligned circumferential

anchors 16, with three being illustrated. The radially expansible scaffold section 12 will typically be balloon expandable and may be formed using a variety of conventional patterns and fabrication techniques as are well-described in the prior art. Many particular patterns and fabrication techniques are described in the patents which are listed in the Background section
5 above, and the teachings of those patents are hereby incorporated by reference herein in their entirety.

[0027] The circumferential anchors 16 will usually extend axially from the scaffold section 12, as illustrated, but in some circumstances the anchors could extend helically, spirally, in a serpentine pattern, or other configurations. It is necessary, however, that the
10 individual circumferential anchors be radially separable so that they can be independently folded, bent, and otherwise positioned within the main body lumen after the scaffold section 12 has been implanted within the branch body lumen. In the schematic embodiment of Fig. 10, the circumferential anchors 16 may be independently folded out in a "petal-like" configuration, as generally shown in broken line for one of the anchors in Figs. 1 and 2.

[0028] In preferred embodiments, the circumferential anchors 16 will be attached to the scaffold section 12 such that they can both bend and rotate relative to an axis A thereof, as shown in broken line in Fig. 1A. Bending will occur radially outwardly and rotation or twisting can occur about the axis A as the anchor is bent outwardly. Such freedom of motion
15 can be provided by single point attachment joints as well as the three-point attachments shown in Fig. 3. Moreover, the expandable and bendable nature of anchors 62 in Fig. 3 will also permit both radially outward bending and twisting and rotation to help the anchors conform to the inside of the main vessel lumen in which they are deployed.

[0029] Referring now to Fig. 3, an exemplary prosthesis structure 50 (shown in a "rolled out" pattern) comprises a scaffold section 52 and a circumferential anchor section 54.

Scaffold section 52 comprises a plurality of radially expansible serpentine cells 56 joined by smaller cells 58 comprising beams and a serpentine ring. The particular pattern illustrated for
25 this structure is well-known and chosen to be exemplary of a useful scaffold. It will be appreciated that a wide variety of other conventional stent structures and patterns would be equally useful as the scaffold section of the prostheses of the present invention.

[0030] The scaffold section 52 is joined to the circumferential anchor section 54 at a plurality of points along a transition line 60. Individual circumferential anchors 62 each
30 comprise four curving elements 66 which reduce in number to three and then to two in the

axial direction away from the transition region 60. The particular structures shown permit radial expansion of the individual anchors as the scaffold is expanded. This is necessary since each circumferential anchor 62 is attached to three adjacent serpentine ring elements in the final serpentine ring 56. Thus, as these serpentine rings 56 are expanded, the circumferential anchor structures will also expand. It would be possible, of course, to join each of the circumferential anchors 62 only at a single location to the scaffold 52, thus allowing the anchors to be deployed without radial expansion.

[0031] The circumferential anchors 62 are curved and have a number of hinge regions which increase their conformability upon circumferential expansion by a balloon, as described hereinafter. Such conformability is highly desirable since the anchors will be expanded under a wide variety of differing conditions which will result in different final geometries for the anchors in use. The final configuration of the anchors in the main vessel lumen will depend on a number of factors, including length of the anchors and geometry of the vasculature and will vary greatly from deployment to deployment. While the anchors together will cover at least a portion of the main vessel wall circumference, most anchors will also be deformed to cover a significant axial length of the main vessel wall as well. Such coverage is schematically illustrated in the figures discussed below.

[0032] Referring now to Figs. 4A-9B, deployment of the stent 10 in accordance with the principles of the present invention will be described. A stent 10 is carried to an os O located between a main vessel lumen MVL and a branch vessel lumen BVL in the vasculature, as shown in Figs. 4A and 4B. Usually, the stent 10 will include at least one radiopaque marker 20 on stent 10 located near the transition region between the scaffold section 12 and the circumferential anchors 16. The radiopaque marker 20 can be aligned with the os O, typically under fluoroscopic imaging. Optionally, the stent 10 may include additional radiopaque markers, such as markers 22 and 24 at the ends of and/or elsewhere on the stent. The stent 10 is delivered by a balloon catheter 30 which may be introduced over a single guidewire GW which passes from the main vessel lumen MVL through the os O into the branch vessel BVL. Optionally, a second guidewire (not shown) which passes by the os O in the main vessel lumen MVL may also be employed.

[0033] After catheter 30 is positioned so that the marker 20 is adjacent the os O, as shown in Figs. 4A and 4B, a balloon 32 which carries the stent is expanded to implant the scaffold region 10 within the branch vessel lumen BVL, as shown in Figs. 5A and 5B. Expansion of

the balloon 30 also partially deploys the circumferential anchors 16, opening them in a petal-like manner, as shown in Fig. 5B, typically extending both circumferentially and axially into the main vessel lumen MVL. The anchors 16, however, are not fully deployed and may remain at least partially within the central region of the main vessel lumen MVL.

5 [0034] In order to fully open the anchors 16, a second balloon catheter 130 is introduced over a guidewire GW to position the balloon 132 within the petals, as shown in Figs. 6A and 6B. Optionally, the first catheter 30 could be re-deployed, for example by partially withdrawing the catheter, repositioning the guidewire GW, and then advancing the deflated balloon 32 within the anchors 16. As it is generally difficult to completely deflate the
10 balloon, however, and a partially inflated balloon would be difficult to pass through the petals 16, it will generally be preferable to use the second balloon catheter 130 for the deforming the petals 16. When using the second balloon catheter 130, a second GW will usually be propositioned in the main vessel lumen MVL past the os O, as shown in Figs. 6A and 6B.

15 [0035] The petals 16 are deformed by inflation of the balloon 132 within the anchors 16, as shown in Figs. 7A and 7B. At this point, the protocol may be completed by withdrawing the second catheter 130, leaving the fully opened and deployed anchors 16 within the main vessel lumen MVL. Usually, however, it will be desirable to place a second stent or other prosthesis 150 within the deformed and deployed circumferential anchors 16 within the main
20 vessel lumen MVL, as shown in Figs. 8A, 8B, 9A and 9B. Catheter 152 is placed over the guidewire GW, typically the same guidewire used to deploy the second catheter 130, to position the stent 150 within the circumferential anchors 16 adjacent the os O (Fig. 8A and 8B). The balloon of the catheter 152 is then inflated to deploy the second stent, as shown in Figs. 9A and 9B. Optionally, another balloon catheter may be used open a passage through
25 the stent 150 into the scaffold within the branch vessel lumen BVL.

[0036] When a second stent or prosthesis is deployed within the expanded anchor structure of the first prosthesis, the combination of the anchors and second stent both contribute to the support of the main vessel and os. In particular, the anchors are supported by the scaffold in the region of the os and over their lengths and tips by the deployed second stent.

30 [0037] While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the

above description should not be taken as limiting the scope of the invention which is defined by the appended claims.